

Section I (Amendments to the Claims)

Please cancel claims 1-19, and amend claims 20, 27, 28, 31, 36, 41, 50 and 55, as set out in the following listing of claims 1-56 of the application.

Claims 1-19. (Canceled)

20. (Currently amended) A gastric occlusive device, comprising: a balloon formed of a multilayer film comprising: a layer of sealing film, having main top and bottom surfaces; and a layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) of thermoplastic polymer film alone lacks such gas barrier character; and an effervescent material contained in said balloon, and arranged for contact with introduced liquid reactive with the effervescent material to liberate gas for inflation of the balloon, wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

21. (Original) The gastric occlusive device of claim 20, wherein the thermoplastic polymer film comprises a thermoplastic polymer selected from the group consisting of polyurethane elastomers, polyester ether elastomers, polyamide elastomers, polyamides, styrenic elastomers, polyvinylchloride, polyvinylethers, ethylene vinyl acetate, polyethylene, polyethylene copolymers, polypropylene copolymers, and combinations of two or more of the foregoing, and wherein when the multilayer film comprises more than one layer of thermoplastic polymer film, each of such layers may be compositionally the same as or different from other layers of thermoplastic polymeric material.

22. (Original) The gastric occlusive device of claim 20, wherein the sealing film comprises a material selected from the group consisting of polyvinylidene chloride (PVDC), polyvinylidene bromide, and ethylene vinyl alcohol polymers.

23. (Original) The gastric occlusive device of claim 20, wherein the thermoplastic polymer film

comprises a thermoplastic polymer selected from the group consisting of polyurethane and polyurethane co-polymers.

24. (Original) The gastric occlusive device of claim 20, wherein the sealing film comprises a material selected from the group consisting of polyvinylidene chloride and EVOH.

25. (Original) The gastric occlusive device of claim 20, wherein the thermoplastic polymer film is formed of polyurethane or a polyurethane co-polymer.

26. (Original) The gastric occlusive device of claim 20, wherein the sealing film comprises polyvinylidene chloride.

27. (Currently amended) The gastric occlusive device of claim 20, wherein the multilayer film comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers ~~has a thickness in a range of from about 0.5 to about 50 mils (0.0127 mm to 1.27 mm).~~

28. (Currently amended) The gastric occlusive device of claim 20, wherein the multilayer film has a thickness in a range of from about 0.5 to ~~about~~ 10 mils (0.0127 mm to 0.254 mm).

29. (Original) The gastric occlusive device of claim 20, wherein the multilayer film has a thickness in a range of from about 2 mils to about 6 mils (0.0508 mm to 0.1524 mm).

30. (Original) The gastric occlusive device of claim 20, wherein the thickness of the sealing film is in a range of from about 0.2 mil to about 6 mil (0.00508 mm to 0.1524 mm).

31. (Currently amended) The gastric occlusive device of claim 20, wherein the thermoplastic polymer film has a thickness in a range of from about 2.0 mils to about ~~20.0~~ 5.0 mils (0.0508 mm to ~~0.508~~ 0.127 mm).

32. (Original) The gastric occlusive device of claim 20, comprising a sealing film of polyvinylidene chloride, having a thickness in a range of from about 0.25 to about 2.0 mil (0.00635 mm to 0.0508 mm), to which a polyurethane elastomer film, having a thickness in a range of from about 2.0 mils to about 5.0 mils (0.0508 mm to 0.127 mm), is extrusion bonded.

33. (Original) The gastric occlusive device of claim 20, wherein two pieces of multilayer film are bonded to one another.

34. (Original) The gastric occlusive device of claim 20, wherein two half-sections of multilayer film are thermoformed, and then bonded to one another.

35. (Original) The gastric occlusive device of claim 20, wherein two pieces of multilayer film are bonded circumferentially to one another to form a 360° seal having a seam devoid of any neck or opening therein.

36. (Withdrawn) A method of therapeutic intervention for treatment of a patient in need of such treatment, said method comprising: introducing to a physiological locus of a patient in need of such therapeutic intervention a balloon formed of a multilayer film, wherein said multilayer film comprises: a layer of sealing film, having main top and bottom surfaces; and a layer of thermoplastic polymer film, on at least one of the main top and bottom surfaces of the sealing film; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) of thermoplastic polymer film alone lacks such gas barrier character; with an effervescent material contained in said balloon, and arranged for contact with introduced liquid reactive with the effervescent material to liberate gas for inflation of the balloon, wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

37. (Withdrawn) The method of claim 36, wherein said balloon comprises two pieces of said multilayer film bonded to one another.

38. (Withdrawn) The method of claim 36, wherein said balloon comprises two half-sections of multilayer film that are thermoformed, and then bonded to one another.

39. (Withdrawn) The method of claim 36, wherein said balloon comprises two pieces of multilayer film that are bonded circumferentially to one another to form a 360° seal having a seam devoid of any neck or opening therein.

40. (Withdrawn) The method of claim 36, further comprising contacting the effervescent material with liquid reactive therewith to liberate gas for inflation of the balloon at said physiological locus.

41. (Currently amended) A gastric occlusive balloon adapted to be inflated by an inflation medium in a gastric cavity of a subject for treatment of said subject, said balloon including a film adapted to retain the balloon in an inflated state for a predetermined period of time sufficient for said treatment of said subject and to deflate after said period of time by egress of said inflation medium through the film, said film comprising a multilayer film including: a layer of sealing film, having main top and bottom surfaces; and a layer of thermoplastic polymer film, laminated to the layer of sealing film, on at least one of the main top and bottom surfaces; wherein the sealing film has a composition and thickness imparting gas barrier character to the multilayer film and wherein the layer(s) of thermoplastic polymer film alone lacks such gas barrier character; wherein said balloon in an inflated state has a diameter in a range of from 3 to 5 inches, said balloon is generally spherical in shape, and said multilayer film has a thickness of up to 10 mils.

42. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film provides a seal that is degradable in exposure to physiological components in said gastric cavity.

43. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film comprises a thermoplastic material.

44. (Previously presented) The gastric occlusive balloon of claim 43, wherein said thermoplastic material comprises the material selected from the group consisting of polyurethane, polyester, and polyamide.

45. (Previously presented) The gastric occlusive balloon of claim 43, wherein said thermoplastic material comprises a material selected from the group consisting of polyethylene, polypropylene, polyvinyl chloride, polyvinylether, ethylene vinyl acetate, and combinations of two or more of the foregoing.

46. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film comprises a material selected from the group consisting of polyvinylidene chloride, polyvinylidene bromide, and ethylene vinyl alcohol polymers.

47. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film comprises polyvinylidene chloride, and polyurethane.

48. (Previously presented) The gastric occlusive balloon of claim 41, wherein the balloon contains an inflation gas-generating reactant.

49. (Previously presented) The gastric occlusive balloon of claim 48, wherein said inflation gas-generating reactant in the presence of water or moisture reacts to form CO₂ gas.

50. (Currently amended) The gastric occlusive balloon of claim 41, wherein the multilayer film comprises up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers ~~having a diameter when inflated in a range of from 3 to 5 inches.~~

51. (Previously presented) The gastric occlusive balloon of claim 41, wherein said balloon is adapted to be inflated by a gas supply tube when the balloon is disposed in the gastric cavity of said subject.

52. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film includes a seam therein.

53. (Previously presented) The gastric occlusive balloon of claim 52, wherein said seam comprises an RF welded seam.

54. (Previously presented) The gastric occlusive balloon of claim 41, wherein said film comprises a degradable seal formed of an ethylene vinyl acetate/hydroxycellulose material that is progressively degradable in the gastric cavity to create an opening in the balloon for deflation of said balloon.

55. (Previously presented) A gastric occlusive balloon adapted to be inflated by an inflation medium in a gastric cavity of a subject for treatment of said subject, said balloon including a film adapted to retain the balloon in an inflated state for a period of time sufficient for said treatment of said subject and to deflate after said predetermined period of time by egress of said inflation

medium through the film, wherein said balloon is generally spherical in shape, wherein said film is a multilayer film having a thickness of up to 10 mils and includes up to 4 thermoplastic polymer film layers, optionally with adhesive between sealing film and thermoplastic polymer film layers, and wherein said film comprises (i) a layer of polyvinylidene chloride or EVOH polymer having a thickness of from about 0.25 to about 2.0 mils (0.00635 mm to 0.0508 mm), and (ii) a layer of polyurethane having a thickness of from about 2.0 to about 5.0 mils (0.0508 mm to 0.127 mm), and said balloon has a diameter when inflated in a range of from 3 to 5 inches.

56. (Previously presented) The gastric occlusive device of claim 20, wherein two pieces of multilayer film are bonded circumferentially to one another to form a 360° seal having a seam with a neck or opening therein.